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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,532	07/19/2002	Daniel R. Soppet	PF168P3	5548

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EXAMINER	
NICHOLS, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,532	SOPPET ET AL.	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) **1-10 (each in part), 14-15 (each in part),** and **21**, drawn to an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 1*, fragments, domains, epitopes encoded therein, variants, and homologues thereof, as well as vectors, host cells, and a method of expressing said nucleic acid(s).

Group 2, claim(s) **1-10 (each in part), 14-15 (each in part),** and **21**, drawn to an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 3*, fragments, domains, epitopes encoded therein, variants, and homologues thereof, as well as vectors, host cells, and a method of expressing said nucleic acid(s).

Group 3, claim(s) **1-10 (each in part), 14-15 (each in part),** and **21**, drawn to an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 5*, fragments, domains, epitopes encoded therein, variants, and homologues thereof, as well as vectors, recombinant host cells, and a method of expressing said nucleic acid(s).

Group 4, claim(s) **11-12** and **16 (each in part)**, drawn to an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 2,* fragments, domains, epitopes, and variants thereof.

Group 5, claim(s) **11-12** and **16 (each in part)**, drawn to an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 4,* fragments, domains, epitopes, and variants thereof.

Group 6, claim(s) **11-12** and **16 (each in part)**, drawn to an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 6,* fragments, domains, epitopes, and variants thereof.

Group 7, claim(s) **13 (in part)**, drawn to an isolated antibody that binds specifically to an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 2,* fragments, domains, epitopes, and variants thereof.

Group 8, claim(s) **13 (in part)**, drawn to an isolated antibody that binds specifically to an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 4,* fragments, domains, epitopes, and variants thereof.

Group 9, claim(s) **13 (in part)**, drawn to an isolated antibody that binds specifically to an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 6,* fragments, domains, epitopes, and variants thereof.

Group 10, claim(s) **17 (in part)**, drawn to a method for preventing, treating, or ameliorating a medical condition comprising administering to a mammalian subject a therapeutically effective amount of an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 2,* fragments, domains, epitopes, and variants thereof.

Group 11, claim(s) **17 (in part)**, drawn to a method for preventing, treating, or ameliorating a medical condition comprising administering to a mammalian subject a therapeutically effective amount of an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 4,* fragments, domains, epitopes, and variants thereof.

Group 12, claim(s) **17 (in part)**, drawn to a method for preventing, treating, or ameliorating a medical condition comprising administering to a mammalian subject a therapeutically effective amount of an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 6,* fragments, domains, epitopes, and variants thereof.

Group 13, claim(s) **18 (in part)**, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising determining the presence or absence of a mutation in an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 1*, fragments, domains, epitopes encoded therein, variants, and homologues thereof.

Group 14, claim(s) **18 (in part)**, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising determining the presence or

absence of a mutation in an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 3*, fragments, domains, epitopes encoded therein, variants, and homologues thereof.

Group 15, claim(s) **18 (in part)**, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising determining the presence or absence of a mutation in an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 5*, fragments, domains, epitopes encoded therein, variants, and homologues thereof.

Group 16, claim(s) **19 (in part)**, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising determining the presence or amount of an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 2*, fragments, domains, epitopes, and variants thereof.

Group 17, claim(s) **19 (in part)**, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising determining the presence or amount of an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 4*, fragments, domains, epitopes, and variants thereof.

Group 18, claim(s) **19 (in part)**, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising determining the presence or amount of an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 6*, fragments, domains, epitopes, and variants thereof.

Group 19, claim(s) **20 (in part)**, drawn to a method of identifying binding partners to the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 2,* fragments, domains, epitopes, and variants thereof.

Group 20, claim(s) **20 (in part)**, drawn to a method of identifying binding partners to the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 4,* fragments, domains, epitopes, and variants thereof.

Group 21, claim(s) **20 (in part)**, drawn to a method of identifying binding partners to the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 6,* fragments, domains, epitopes, and variants thereof.

Group 22, claim(s) **22 (in part)**, drawn to a method of identifying an activity in a biological assay comprising expressing an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 1*, fragments, domains, epitopes encoded therein, variants, and homologues thereof and detecting activity in a biological assay.

Group 23, claim(s) **22 (in part)**, drawn to a method of identifying an activity in a biological assay comprising expressing an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 3*, fragments, domains, epitopes encoded therein, variants, and homologues thereof and detecting activity in a biological assay.

Group 24, claim(s) **22 (in part)**, drawn to a method of identifying an activity in a biological assay comprising expressing an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 5*, fragments, domains, epitopes encoded therein, variants, and homologues thereof and detecting activity in a biological assay.

Group 25, claim(s) **23**, drawn to a product.

Group 26, claim(s) **24-25 (each in part)**, drawn to a method for preventing, treating, or ameliorating a medical condition comprising administering to a mammalian subject a therapeutically effective amount of an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 1*, fragments, domains, epitopes encoded therein, variants, and homologues thereof.

Group 27, claim(s) **24-25 (each in part)**, drawn to a method for preventing, treating, or ameliorating a medical condition comprising administering to a mammalian subject a therapeutically effective amount of an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 1*, fragments, domains, epitopes encoded therein, variants, and homologues thereof.

Group 27, claim(s) **24-25 (each in part)**, drawn to a method for preventing, treating, or ameliorating a medical condition comprising administering to a mammalian subject a

therapeutically effective amount of an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 1*, fragments, domains, epitopes encoded therein, variants, and homologues thereof.

4. According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. All the groupings pertain to a human neuropeptide receptor but each group has a different special technical feature not shared by the remaining groups.

Group 1 has the special technical feature of a polynucleotide sequence of *SEQ ID NO: 1* not shared by any of the remaining groups.

Group 2 has the special technical feature of a polynucleotide sequence of *SEQ ID NO: 3* not shared by any of the remaining groups.

Group 3 has the special technical feature of a polynucleotide sequence of *SEQ ID NO: 5* not shared by any of the remaining groups.

Group 4 has the special technical feature of a polypeptide sequence of *SEQ ID NO: 2* not shared by any of the remaining groups.

Group 5 has the special technical feature of a polypeptide sequence of *SEQ ID NO: 4* not shared by any of the remaining groups.

Group 6 has the special technical feature of a polypeptide sequence of *SEQ ID NO: 6* not shared by any of the remaining groups.

Group 7 has the special technical feature of a polypeptide sequence of an isolated antibody that binds specifically to an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 2,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 8 has the special technical feature of a polypeptide sequence of an isolated antibody that binds specifically to an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 4,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 9 has the special technical feature of a polypeptide sequence of an isolated antibody that binds specifically to an isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 6,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 10 has the special technical feature of a therapeutic method using the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 2,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 11 has the special technical feature of a therapeutic method using the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 4,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 12 has the special technical feature of a therapeutic method using the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 6,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 13 has the special technical feature of a mutation in the isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 1*, fragments, domains, epitopes encoded therein, variants, and homologues thereof not shared by any of the remaining groups.

Group 14 has the special technical feature of a mutation in the isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 3*, fragments, domains, epitopes encoded therein, variants, and homologues thereof not shared by any of the remaining groups.

Group 15 has the special technical feature of a mutation in the isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 5*, fragments, domains, epitopes encoded therein, variants, and homologues thereof not shared by any of the remaining groups.

Group 16 has the special technical feature of a diagnostic method using the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 2,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 17 has the special technical feature of a diagnostic method using the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 4,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 18 has the special technical feature of a diagnostic method using the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 6,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 19 has the special technical feature of identifying binding partners to the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 2,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 20 has the special technical feature of identifying binding partners to the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 4,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 21 has the special technical feature of identifying binding partners to the isolated polypeptide consisting of the polypeptide sequence of *SEQ ID NO: 6,* fragments, domains, epitopes, and variants thereof not shared by any of the remaining groups.

Group 22 has the special technical feature of identifying an activity in a biological assay comprising expressing an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 1*, fragments, domains, epitopes encoded therein, variants, and homologues thereof and detecting activity in a biological assay not shared by any of the remaining groups.

Group 23 has the special technical feature of identifying an activity in a biological assay comprising expressing an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 3*, fragments, domains, epitopes encoded therein, variants, and homologues thereof and detecting activity in a biological assay not shared by any of the remaining groups.

Group 24 has the special technical feature of identifying an activity in a biological assay comprising expressing an isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 5*, fragments, domains, epitopes encoded therein, variants, and homologues thereof and detecting activity in a biological assay not shared by any of the remaining groups.

Group 25 has the special technical feature of a product not shared by any of the remaining groups.

Group 26 has the special technical feature of a therapeutic method using the isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 1*, fragments, domains, epitopes encoded therein, variants, and homologues thereof not shared by any of the remaining groups.

Group 27 has the special technical feature of a therapeutic method using the isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 3*, fragments, domains, epitopes encoded therein, variants, and homologues thereof not shared by any of the remaining groups.

Group 28 has the special technical feature of a therapeutic method using the isolated nucleic acid consisting of the polynucleotide sequence of *SEQ ID NO: 5*, fragments, domains, epitopes encoded therein, variants, and homologues thereof not shared by any of the remaining groups.

5. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

6. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

7. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Summary

11. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Elizabeth C. Kemmerer

CJN
June 15, 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER